REMARKS

Status of the Claims.

Claims 1-3, and 4-8 are pending with entry of this amendment, claims 5, and 9-17 being cancelled and no claims being added. Claim 1 is amended herein. This amendment introduces no new matter. Support is replete throughout the specification.

25 U.S.C. §112, first paragraph.

Claims 1-8 were rejected under 35 U.S.C. §112, first paragraph, as allegedly not enabled for screening for the presence of alcoholic cirrhosis of the liver in any and all mammals.

Claim 1 is amended herein to recite:

> 1. A method of screening for the presence of cirrhosis of the liver in a **human suspected of having cirrhosis of the liver**, said method comprising measuring the level of YKL-40 in a biological sample of the **patient**; and comparing the level to that of a normal, healthy human, wherein a statistically significant difference is an indicator for the presence of cirrhosis of the liver **in said patient**.

The claims are now directed to screening for the presence of cirrhosis of the liver **in a human suspected of having cirrhosis of the liver**. The claimed invention is thus commensurate in scope with the disclosure and the examples provided therein (indeed it is narrower in scope than the disclosure), and no undue experimentation is required to practice the claimed method. Accordingly, the rejection of claims 1-8 under 35 U.S.C. §112, first paragraph, should be withdrawn.

35 U.S.C. §112, second paragraph.

Claims 1-8 were rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite. In particular the Examiner alleged that claim 1 is confusing because YKL-40 is used in combination of other indicators to make a differential diagnosis of cirrhosis of the liver, but it is allegedly "unclear what "other indicators" may be used to make a differential diagnosis since these other indicators are not clearly stat[ed] in the claims." In addition the claim was allegedly confusing because it is not a claim directed to a "differential diagnosis" of cirrhosis of the liver. Applicants traverse.

The Examiner is respectfully reminded that "a patent need not teach and preferably omits, what is well-known in the art." *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 94 (Fed. Cir. 1986) cert. denied 480 U.S. 947 (1987).

In the instant case the claims recite

> 1. A method of screening for the presence of cirrhosis of the liver in a human suspected of having cirrhosis of the liver, **said method comprising** . . .

The open (comprising) language recognizes that the method of screening for cirrhosis of the liver can include steps and factors other than those enumerated in the claims. Similarly, the last line of the claim recites:

> . . . wherein a statistically significant difference **is an indicator** for the presence of cirrhosis of the liver in said patient.

recognizing that the YKL-40 level is simply one indicator of the recited condition (cirrhosis).

Other indicators of cirrhosis and the elements of a differential diagnosis of cirrhosis are well known to those of skill in the art and thus need not be taught in the specification or recited in the claims (*see, e.g., Hybritech, Inc. supra*). For example, known indicators of cirrhosis include, but are not limited to jaundice, palmar erythema, spider angiomas, parotid and lacrimal gland enlargement, clubbing of fingers, splenomegaly, muscle wasting, and ascites with or without peripheral edema, testicular atrophy in men, signs of virilization or menstrual irregularies in women, anemia, nutritional deficiency (notably of folic acid and vitamin B12), hypersplenism, leukocytosis, hyperbilirubinemia, and the like (*see, e.g.,* Harrison's Principles of Internal Medicine, thirteenth edition, page 1485).

Indicators of cirrhosis are thus clearly well known and therefore, contrary to the Examiner's assertion, under prevailing law need not be set forth in the claims.

With respect to the Examiner's comments that the claims do not recite a "differential diagnosis", and are therefore indefinite, Applicants note that essentially every clinical diagnostic assay is performed in the context of a differential diagnosis. **No doctor relies solely on a single diagnostic assay to the exclusion of consideration of the other factors typically indicative of the condition under consideration.** Nevertheless, it is common practice for patents directed to diagnostics to simply recite the method pertaining to the inventive contribution of the subject patent.

Thus, for example U.S. Patent 6,689,561 recites:

> 18. A method for diagnosing a cancer condition in a human comprising detecting CDK4I in a biological cell sample from the human which sample is suspected of containing premalignant or malignant cells.

The claim simply recites detection of CDK4I. Nevertheless, in a diagnosis of cancer, a physician would not rely solely on the detection of CDK4I for the diagnosis of cancer. The recited method would clearly be performed in the context of a differential diagnosis. Yet, in accordance with *Hybritech, Inc.*, Applicants were not required to recite the elements of the differential diagnosis for the claim to be allowed.

Similarly, U.S. Patent 6,645,725 recites:

> 1. A method for diagnosing endometriosis in a patient, said method comprising:
>
> (a) obtaining an antibody-containing tissue or an antibody-containing fluid sample from said patient,
>
> (b) incubating an antigen with said sample, wherein said antigen comprises a Gal.beta.1-3GalNAc disaccharide moiety,
>
> (c) detecting autoantibody reactivity of said sample to said antigen, and;
>
> (d) correlating an increased level of autoantibody reactivity with a normal level to diagnose endometriosis in said patient.

Again the assay simply pertains to the detection of an autoantibody reactive to a particular antigen for the diagnosis of endometriosis. Nevertheless, in practice this assay would be performed in the context of a differential diagnosis for endometriosis. However, in accordance with *Hybritech, Inc.*, Applicants were not required to recite the elements of the differential diagnosis for the claim to be allowed.

Given the elements/factors of a differential diagnosis of cirrhosis are known to those of skill in the art, the Examiner's assertion that the claims are indefinite because of the failure to recite factors of the differential diagnosis and/or because of the failure to recite "differential diagnosis" in the claim is simply inconsistent with prevailing law and prevailing Patent Office Practice.

Accordingly, the Examiner's rejection under 35 U.S.C. §112, second paragraph, is improper and should be withdrawn.

In view of the foregoing, Applicants believes all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. Should the Examiner seek to maintain the rejections, Applicants request a telephone interview with the Examiner and the Examiner's supervisor.

If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (510) 769-3513.

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